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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,988	07/05/2001	Yuta Nakai	210669US0	1677

38108 7590 07/28/2006

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EXAMINER	
MARVICH, MARIA	
ART UNIT	**PAPER NUMBER**
1633	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,988	NAKAI ET AL.	
	Examiner	Art Unit	
	Maria B. Marvich, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,7 and 11-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7 and 11-14* is/are rejected.

7)☒ Claim(s) *6 and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to an amendment filed 5/11/06. Claims 2-5 and 8-10 have been cancelled. Claims 11-14 have been added. Claims 1, 6 and 7 have been amended. Claims 1, 6, 7 and 11-14 are pending.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are no new grounds of rejection herein and therefore, this action is final.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Ciccognani et al (FEMS Microbiology Letters 94, 1992, page 1-6; see entire document). **This rejection is maintained for reasons of record in the office action mailed 1/12/06 and restated below. The rejection has been extended to newly added claims 12-14.**

Ciccognani et al teach methods of culturing *E. coli* (RG145), which according to the instant specification comprise a high and low-energy efficiency respiratory chain pathway.

RG145 is a genetic recombinant strain in which an enzyme of the high-energy efficiency pathway was enhanced and an enzyme of low-energy efficiency was deficient. The cells within the media comprise nucleic acid or L-amino acid and were collected resulting in collection of the nucleic acid and L-amino acid. This inherently encompasses L-lysine, L-threonine and L-phenylalanine. The cells contain a chromosomal deletion resulting in the inability of the cell to express *cydA* and contain a cosmid containing the *cyo* operon resulting in over expression of the cytochrome bd complex (page 2, section 3.1) as recited in claims 1, 7 and 12-14.

Claims 1, 7 and 12-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Spehr et al (Biochemistry, 1999, Vol 38, pages 16261-16267; see entire document). **This rejection is maintained for reasons of record in the office action mailed 1/12/06 and restated below. The rejection has been extended to newly added claims 12-14.**

Spehr et al teach methods of culturing *E. coli* cells (ANN003/pAR1219), which according to the art and the instant specification comprise a high and low-energy efficiency respiratory chain pathway. ANN003/pAR1219 is a genetic recombinant strain in which an enzyme of the high-energy efficiency pathway was enhanced. The cells within the media comprise nucleic acid or L-amino acid and were collected resulting in collection of the nucleic acid and L-amino acid. This inherently encompasses L-lysine, L-threonine and L-phenylalanine. The *nuo* operon was cloned and expressed under control of the inducible T7Φ10 promoter in *E. coli* cells for overexpression as recited in claims 1, 7 and 12-14.

Response to Argument

Applicants traverse the claim rejections under 35 U.S.C. 102 on pages 8-10 of the amendment filed 5/12/06. Applicants argue that neither Ciccognani et al nor Spehr et al teach that the target substance is produced and accumulates in the medium. As well, applicants argue that the methods of Ciccognani et al do not teach or suggest excretion of any target substance in the medium, let alone collection of any such substance. Finally, applicants argue that the instant strain has an inherent ability to produce and accumulate target substance in the medium when the strain is cultured in the medium, which is not inherently or explicitly taught by the prior art.

Applicants' arguments filed 5/12/06 have been fully considered but they are not persuasive. First, applicants argue that the prior art does not teach excretion into the medium of target substances. However, applicants are reading limitations into the claims that do not exist. Rather, the claims are drawn to *E. coli* strains that produce and accumulate target substances in the medium. There is no explicit or inherent requirement that the strain excrete these target substances. In fact, the specification does not disclose that the strains excrete the target substances that are to be produced. As to the ability of the prior art strains to produce and accumulate nucleic acids and L-amino acids, any *E. coli* strain is capable of naturally accumulating pathways nucleic acid and L-amino acids within the cell and outside of the cell through cellular lysis or rupture or through native excretion during normal growth and replication processes. The step of collecting the cells or medium would lead to collection of the target substances. Secondly, neither the cells nor steps within the recited method comprise additional components that are distinguishable from the prior art. The prior office action has set forth that the argued differences between the prior art fibers and that of the instant invention are

unclear. Hence, if the recited strains are the same then the inherent ability of the instant strain to accumulate the target substances outside of the cell should be true for the prior art strains. Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See in re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Conclusion

Claims 1, 7 and 12-1 are rejected.

Claims 6 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications and (571) 273-8300 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maria B Marvich, PhD
Examiner
Art Unit 1633

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER